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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,737	01/16/2001	Alan Wayne Henley	7175-67612	7500

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Barnes & Thornburg
11 South Meridian Street
Indianapolis, IN 46204

EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,737

Applicant(s)

HENLEY ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/11/02, 5/7/02 and 7/2/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-35 and 45-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32 is/are allowed.
- 6) ☒ Claim(s) 33-35, 45-53, 55-63, 65-73, and 75-85 is/are rejected.
- 7) ☒ Claim(s) 54 and 64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

DETAILED ACTION

Response to Amendment

1. The preliminary amendment filed on 4/1/02 has been received and made of record in the application file wrapper. Claims 45-85 have been added.
2. The response filed 7/2/02 has also been received. The examiner acknowledges that applicant's preliminary amendment was filed before the mailing of the first office action. As such, the examiner is issuing a new office action, which replaces the office action of paper no.7, mailed 6/19/02.

Information Disclosure Statement

3. The information disclosure statement papers filed 5/7/02 have been received and made of record in the application file wrapper. Note the acknowledged PTO-1449 form attached hereto.

Drawings

4. The drawings are objected to because:
Nebulizer "26" is not shown in Fig. 1 as indicated on page 6, lines 28-32.
"19" is missing from fig. 3 as indicated on page 8, line 5;
"46", "48" and "50" are not shown on Figs. 2 and 3 as indicated on page 8, line 5;
"94" is not shown on Fig. 2 as indicated on page 13, line 9;
Adhesive "158" is not shown in the drawings; and

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In Fig. 11, drainage "24" is not labeled. Correction is required.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "22" and "24".

6. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities:

Page 8, line 16" nebulizer output port "28" was previously designated as "30";

Page 10, line 14, the applicant refers to "68" as a water trap then refers to "68" as a pressure sensor on page 6, line 5;

Page 11, line 22, "selector valve 60" should read --selector valve 58--;

Appropriate correction is required.

Claim Objections

8. Throughout the claims the applicant recites "at least one passageways". This phrase should be changed to --at least one passageway--.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claim 33 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,398,767 ("Fleischmann").

As regards claim 33, Fleischmann discloses a wound treatment apparatus comprising a bandage (10) having a fluid drainage passageway therein for insertion of a fluid drainage tube (16). Fleischmann further discloses first and second drainage receptacles (24, 28) coupled to the drainage tube, and first and second valves (32, 34) in the form of clamps coupled between the fluid drainage tube and the first and second drainage receptacles.

The applicant should note that both receptacles, because of the configuration of the tubing, could be used to drain the wound.

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11. Claims 45-47, 55, 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated WO 91/00718 ("Svedman").

As regards claims 45, 46, 55, 66 and 67, Svedman discloses an irrigation dressing comprising a negative pressure source (syringe 12), a fluid source (irrigation liquid), first sheet (flexible plate 1) and second sheet (adhesive layer 3) each having a plurality of apertures/passageways communicating with one another for adding to or removing fluid from the wound of a user.

As regards claims 47, 68, the first and second sheets are aligned about their perimeters.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1,549,756 ("Westaby et al.") in view of Fleischmann.

Regarding claims 33 and 34, Westaby et al. substantially disclose all features of the claimed invention including a wound irrigation device comprising, a bandage configured including a wound backing surface configured to face toward the wound and a fluid drainage passageway having an opening adjacent the wound facing surface and a fluid drainage tube coupled to the fluid drainage passageway (col. 2, lines 40-50, col. 2, lines 53-65, and Fig. 1).

Westaby et al. fail to teach first and second fluid drainage receptacles coupled to the drainage tube and first and second valves coupled between the fluid drainage tube and first and second fluid drainage receptacles, respectively.

Fleischmann discloses a wound treatment device comprising first and second fluid drainage receptacle (24, 28) coupled to a fluid drainage tube (16) for the purpose of containing the fluid removed from the wound site. In view of Fleischmann, it would

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have been obvious to one having ordinary skill in the art to modify Westaby et al. by adding fluid drainage receptacles for the purpose of containing the fluid removed from the wound site. The applicant should note that both receptacles, because of the configuration of the tubing, could be used to drain the wound.

As regards the valves, Fleischmann pinch valves, in the form of first and second closure mechanisms (clamps) (32, 34).

As regards claim 35, both Westaby et al. and Fleischmann fail to teach a sensor. However, the examiner contends that sensors of all kinds are well known in the art, and the addition of such to a prior art either Westaby et al. or Fleischmann would include only routine skill in the art.

16. Claims 45, 49-53, 55-57, 60-62, 64, 66, 60-73, 76,77, 80-83 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westaby et al.

As regards claims 45, 50, 51, 55, 60, 61, 66, 70, 71, 76, 80, 81 and 85, Westaby et al. disclose a flexible, transparent cover/sheet having a plurality of apertures/passageways (20, 22) through which fluid may be added to or removed from a wound (page 2, lines 5-11 and lines 5-59).

Westaby et al. fail to teach a negative pressure source. However, the examiner contends that one having ordinary skill in the art would have found it obvious to connect a negative pressure source to the outlet in order to remove fluid from the wound site. Such a configuration is conventionally known in the wound irrigating art.

Additionally, the examiner wishes the applicant to note that the device of Westaby et al., once modified to include the vacuum source, is **capable** of

communicating negative pressure established by the vacuum source through the apertures/passageways.

As regards claim 49, Westaby et al. fail to teach the plurality of apertures/passageways are arranged in a circle. Absent a critical teaching and/or a showing of unexpected results derived from placing the apertures/passageways in a circle, the examiner contends that such a configuration is an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claim 52, Westaby et al. disclose the cover/sheet is constructed from a synthetic plastics material. Westaby et al. fail to teach the cover/sheet is impermeable. However, given the environment in which the device is used, the examiner contends that one having ordinary skill in the art would have been motivated to construct the cover/sheet from an impermeable plastic material in order to both prevent the fluid added to the wound site from escaping through the cover/sheet and to prevent the fluid from the wound from escaping and contaminating the surrounding environment.

As regards claim 53, note rim (14).

As regards claim 56, one aperture/passageway removes fluid from the wound that was added by the other aperture/passageway.

As regards claim 57, note the rejection of claim 49 above.

As regards claim 62, note the rejection of claim 52 above.

As regards claim 64, note the rejection of claim 53 above.

As regards claim 69, note the rejection of claim 49 above.

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As regards claim 72, note the rejection of claim 52 above.

As regards claim 73, note the rejection of claim 53 above.

As regards claim 75, the apertures/passageways are **capable** of communicating fluid from the fluid source once modified.

As regards claim 77, note the rejection of claim 49 above.

As regards claim 82, note the rejection of claim 52 above.

As regards claim 83, note the rejection of claim 53 above.

As regards claim 85, see the rejection of claim 75 above.

17. Claims 48 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westaby et al. in view of U.S. Patent No. 6,142,982 ("Hunt et al.").

As regards claims 48 and 63, Westaby et al. fail to teach a multi-lumen tube coupled to the bandage. However, Hunt et al. teach it is conventional in the art to couple a multi-lumen tube to a bandage for the purpose decreasing the amount of separate tubes supplied to the bandage.

In view of Hunt et al., it would have been obvious to one having ordinary skill in the art to modify the bandage of Westaby et al. by replacing the separate tubing with a multi-lumen tube for the purpose of decreasing the amount of separate tubes supplied to the bandage.

18. Claims 55, 58, 59, 76, 78 and 79 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,953,565 ("Tachibana et al").

As regards claims 55, 58, 59, 76, 78 and 79, Tachibana et al. disclose a device capable of treating a wound comprising a first sheet/bandage (11) having a plurality of apertures/passageways through which the fluid delivery and fluid drainage conduits are inserted, a second sheet/bandage (14) having a perimeter and being both aligned and coupled with the perimeter of the first sheet/bandage, and a fluid source (18). The applicant should note that the second sheet does not have any apertures, thereby having a lesser number of apertures than the first sheet.

Tachibana et al. fail to teach a negative pressure source. However, the examiner contends that one having ordinary skill in the art would have found it obvious to connect a negative pressure source to the discharge conduit in order to remove fluid from the wound site. Such a configuration is conventionally known in the wound irrigating art.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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20. Claims 45, 49-52, 55, 57, 61, 62, 66, 69-72, 75-77, 80-82 and 85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, 24, 25, 28 and 37 of U.S. Patent No. U.S. Patent No. 6,458,109 ("the '109 patent"). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims arguably broader than claims 23,24,25, 28 and 37 of the '190 patent which encompasses the same metes, bounds and limitations. Therefore, it would be obvious to eliminate the limitations of the narrower claims, since it has been held that omission of an element and its function and a combination where the remaining elements perform the same functions as before involves only routine skill in the art. See *In re Karlson*, 136 USPQ 184.

Additionally, '190 patent fails to state that the sheet/bandage is clear. The examiner contends that it would have been obvious to one having ordinary skill in the art to modify the sheet of the '190 patent to include a clear sheet in order to view the wound site. Applicant should also note that it would have been obvious to one having ordinary skill in the art to use the vacuum to remove fluid from the wound site.

Allowable Subject Matter

21. Claim 32 is allowed.

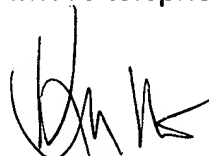
22. Claims 54, 65 and 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays and Thursdays from 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703.305.3590 for regular communications and 703.305.3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



Kim M. Lewis
Primary Examiner
Art Unit 3761

kml
October 21, 2002